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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.
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000000000 05/27/99  
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HR032/16927

EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

05/27/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/828,323

Applicant(s)  
O'Donnell

Examiner  
Einar Stole

Group Art Unit  
1653



☒ Responsive to communication(s) filed on Jun 8, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 5-8, 10, 12-17, 19, 20, 54, 55, 57-60, 62, 64, and 65 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 5-7, 12-16, 19, 20, 54, 55, 57-60, 64, and 65 is/are rejected.

☒ Claim(s) 8, 10, 17, and 62 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. Claims 9, 11, 18, 21-53, 56, 61, 63, and 66-75 has been canceled by the Amendment of June 8, 1999 (Paper No. 15). Claims 5-8, 10, 12-17, 19, 20, 54, 55, 57-60, 62, 64, and 65 are still pending.

#### ***Specification***

2. Applicant has canceled the new matter presented by amendment of the specification at page 17 by the Amendment of August 5, 1997 (Paper No. 12). In addition, Applicant's submission of a substitute paper copy, CRF and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

#### ***Terminal Disclaimer***

3. The terminal disclaimer filed on June 8, 1999 (Paper No. 17), disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 5,668,004, has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Claim Objections***

4. Claims 8, 10, 17, and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19 and 20 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is explained in the previous Office action. Applicant's Declaration under 37 CFR 1.132, filed June 8, 1999 (Paper No. 16) does not overcome the rejection of claims 19 and 20, under 35 USC 112, first paragraph, because the Declaration relies on teachings published after the filing date of the application. The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 190 USPQ 402 (CCPA 1976). A later dated publication, although it cannot supplement an insufficient disclosure in a prior dated application to make it enabling, can, however, offer the later dated publication as evidence of the level of skill in the art at the time the invention was filed when submitted as testimony of an expert, as is the case here. *Gould v. Quigg*, 822 F.2d 1074, 3 USPQ2d 1302 (Fed. Cir. 1987); see also MPEP 2164.05(a). The information provided by the later published documents is directed to the relatedness and specific sequences of the  $\delta$  and  $\delta'$  subunits of eubacterial DNA polymerase III.

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The rejection of claims 19 and 20, under 35 USC 112, first paragraph, is directed to the non-enablement of the instant specification for subunits of DNA polymerase III holoenzyme for polypeptides of any sequence or structure and is based on the unpredictability of the art with regard to structure function relationships and the lack of guidance provided by the prior art. Thus, reference to the later published documents to overcome the rejection of claims 19 and 20, under 35 USC 112, first paragraph, relies on the ability of these references to supplement an insufficient disclosure by the instant application.

7. Claims 5-7, 12, 13, 59, 64, and 65 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is explained in the previous Office action. Applicant's Declaration under 37 CFR 1.132, filed June 8, 1999 (Paper No. 16) does not overcome the rejection of claims 5-7, 12, 13, 59, 64, and 65, under 35 U.S.C. 112, first paragraph, because the Declaration relies on teachings published after the filing date of the application. Claims 5-7, 12, 13, 59, 64, and 65 drawn to a genus of nucleic acids encoding  $\delta$  and  $\delta'$  subunits of DNA polymerase III from eubacterial sources. The instant claims and specification do not specifically define, in structural terms, any of the claimed nucleic acids from any other source than *Escherichia coli*. Thus, while the instant claims are directed to a genus of DNA molecules encoding DNA polymerase III subunits, the specification fails to provide any representative species of such subunits. Moreover, the specification fails to describe any

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representative species by any identifying characteristics or properties other than the functionality of the subunit encoded by the claimed DNA molecules. Given this lack of representative DNA species, Applicant has failed to sufficiently described the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the claimed invention. Although the predictability of the art is a factor considered in the analysis of a claim drawn to a genus of nucleic acids, this determination must be made at the time the invention was made. Thus, Applicant's Declaration under 37 CFR 1.132, filed June 8, 1999 (Paper No. 16) does not overcome the rejection of claims 5-7, 12, 13, 59, 64, and 65 stand rejected under 35 U.S.C. 112, first paragraph, because the Declaration relies on teachings published after the filing date of the application and does not demonstrate a predictable art at the time the invention was made.

8. Claims 14-16, 54, and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is explained in the previous Office action. Applicant's Declaration under 37 CFR 1.132, filed June 8, 1999 (Paper No. 16) does not overcome the rejection of claims 14-16, 54, and 57, under 35 U.S.C. 112, first paragraph, because the Declaration relies on teachings published after the filing date of the application. Claims 14-16, 54, and 57 drawn to a genus of  $\delta$  and  $\delta'$  subunits of DNA polymerase III from eubacterial sources. The instant claims and specification do not specifically define, in structural terms, any of the claimed subunits from any other source than

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*Escherichia coli*. Thus, while the instant claims are directed to a genus of DNA polymerase III subunits, the specification fails to provide any representative species of such subunits. Moreover, the specification fails to describe any representative species by any identifying characteristics or properties other than the functionality of the subunit encoded by the claimed molecules. Given this lack of representative species, Applicant has failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the claimed invention. Although the predictability of the art is a factor considered in the analysis of a claim drawn to a genus of subunits, this determination must be made at the time the invention was made. Thus, Applicant's Declaration under 37 CFR 1.132, filed June 8, 1999 (Paper No. 16) does not overcome the rejection of claims 14-16, 54, and 57 stand rejected under 35 U.S.C. 112, first paragraph, because the Declaration relies on teachings published after the filing date of the application and does not demonstrate a predictable art at the time the invention was made.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 59, 60, 64 and 65 stand rejected under 35 U.S.C. 102(b) as being anticipated by Takase et al. Claims 59, 60, 64 and 65 are drawn to the DNA molecules encoding the isolated, segregated  $\delta$  subunit of the DNA polymerase III from *Escherichia coli*.

Takase et al. teach the *Escherichia coli rlpA* gene, which encodes a 36 kDa protein, its isolation and expression. Applicant's arguments, filed on June 8, 1999 as Paper No. 15, which reiterate the discussion of the prior art teachings of Takase et al. present in the Declaration under 37 CFR 1.132, filed on December 17, 1996 in the parent application, 08/279,058, and resubmitted here as Paper No. 16, have been fully considered but they are not persuasive. The claimed sequence, the 1032 nucleotides of SEQ ID NO: 6, were compared with sequences of the prior art using MPSearch sequence analysis software employing the Smith-Waterman algorithm and using the default Table and a gap penalty of 6. The claimed DNA molecule, corresponding to SEQ ID NO: 6 and the nucleic acids encoding the protein described by SEQ ID NO: 9, is 100% identical to the nucleotide sequence taught by Takase et al. The Declaration under 37 CFR 1.132 filed on December 17, 1996 in the parent application, 08/279,058, and resubmitted here as Paper No. 16, is insufficient to overcome the rejection of claims 59, 60, 64 and 65 based upon Takase et al. as applied under 35 USC § 102(b) as set forth in the last Office action, because the Declaration fails to set forth facts supporting the conclusions presented in the Declaration. Applicant asserts that the sequences disclosed by the instant application are not identical to the nucleotide sequence taught by Takase et al. The Applicant cites references which support the assertion that the nucleotide sequence taught by Takase et al. is erroneous. Regardless of the accuracy of the reported sequences, sequence analysis of the nucleotide



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sequences disclosed by Takase et al. show that a sequence taught by Takase et al. is 100% identical to the nucleotide sequence described by SEQ ID NO: 6. Furthermore, the references relied upon by the Applicant in the Declaration do not qualify as prior art. Thus, the teachings of these references are not available to demonstrate the state of the art at the time the invention was made. Therefore, the Declaration of December 17, 1996, with regard to the prior art teachings of Takase et al. does not present facts sufficient to overcome the rejection of claims 59, 60, 64 and 65 based upon Takase et al. as applied under 35 USC § 102(b).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 54, 55, 57-60, 64 and 65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Takase et al. Claims 54, 55, 57 and 58 are drawn to the isolated, segregated  $\delta$  subunit of the DNA polymerase III from *Escherichia coli*. Claims 64 and 65 are drawn to the expression of the  $\delta$  subunit of the DNA polymerase III from *Escherichia coli* and host cells transformed with nucleic acids encoding the  $\delta$  subunit of the DNA polymerase III.

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Takase et al. teach the *Escherichia coli rlpA* gene, which encodes a 36 kDa protein, its isolation and expression. The claimed nucleotide sequence, the 1032 nucleotides described by SEQ ID NO: 6, were compared with sequences of the prior art using MPSearch sequence analysis software employing the Smith-Waterman algorithm and using the default Table and a gap penalty of 6. The DNA molecules encoding the  $\delta$  subunit of DNA polymerase III disclosed in the instant application, which corresponds to SEQ ID NO: 6, is identical to the nucleotide sequence taught by Takase et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to express the nucleic acids taught by Takase et al., because techniques for the expression of isolated genes were well known in the art at the time the invention was made, and the skilled artisan would have been motivated to isolate the expressed gene product.

### ***Conclusion***

13. No claims are allowable. Claims 8, 10, 17, and 62 are allowable over the prior art of record.
14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

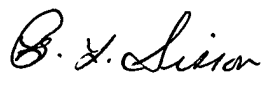
16. The Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Einar Stole, Ph.D., whose telephone number is (703)-305-4507. The Examiner can normally be reached Tuesday through Friday 6:30 a.m. to 5:00 p.m.

If attempts to reach the Examiner are unsuccessful, the Examiner's supervisor, Bradley Sisson, can be reached on (703)-308-3978. The fax phone number for Technology Center 1600 is (703)-305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703)-308-0196.

August 26, 1999

  
BRADLEY SISSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
8/26/99

361 CAAGAAAATCCCGCTGGTTACTGCGCTTGGCAATCGACGTGACCTGTCTAG 420  
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1021 ATGACGCGTTGA 1032

3  
RESULT  
LOCUS 1261 bp DNA BCT 23-JUL-1993  
DEFINITION Escherichia coli (clone pUC-delta) DNA polymerase III delta subunit (hola) gene, complete cds.  
ACCESSION 5145728  
NID 5145728  
KEYWORDS DNA polymerase III delta subunit; hola gene.  
SOURCE Escherichia coli (strain K-12) (library: lambda-phage of Y. Kohara)  
ORGANISM Escherichia coli  
Eubacteria; Proteobacteria; gamma subdivision; Enterobacteriaceae; Escherichia.

REFERENCE  
AUTHORS Takase, I., Ishino, F., Wachi, M., Kamata, H., Doi, M., Asoh, S., Matsunawa, H., Ohta, T. and Matsunashi, M.  
TITLE Genes encoding two lipoproteins in the leus-daca region of the Escherichia coli chromosome  
JOURNAL J. Bacteriol. 169, 5692-5699 (1987)  
MEDLINE 88058785  
REFERENCE 2 (bases 1 to 1261)  
AUTHORS Dong, Z., Onrust, R., Skangalis, M. and O'Donnell, M.  
TITLE DNA polymerase III accessory proteins. I. hola and holo encoding delta and delta  
JOURNAL J. Biol. Chem. 268, 11758-11765 (1993)  
MEDLINE 93280136  
FEATURES  
Location/Qualifiers

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BASE COUNT 293 a 326 c 337 g 305 t  
ORIGIN

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Best Local Similarity 100.0%; Pred. No. 0.00e+00;  
Matches 1032; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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 ACCESSION M94267  
 KEYWORDS 9145784  
 NID DNA polymerase III delta subunit.  
 SOURCE Escherichia coli (strain MAF102) DNA.  
 ORGANISM Escherichia coli  
 Eubacteria: Proteobacteria: gamma subdivision: Enterobacteriaceae: Escherichia.  
 REFERENCE 1 (sites)  
 1. Ishino, F., Machi, M., Kamata, H., Doi, M., Aosh, S., Matsuzawa, H., Ohla, T., and Matsushashi, M.  
 Genes encoding two lipoproteins in the leus-daca region of the Escherichia coli chromosome  
 J. Bacteriol. 189, 5692-5699 (1987)

MEDLINE 88058785  
 REFERENCE 2 (bases 1 to 1147)  
 AUTHORS Carter, J.C., Franden, M.A., Abersold, R.H., and McHenry, C.S.  
 TITLE Molecular cloning, sequencing, and overexpression of the structural gene encoding the delta subunit of Escherichia coli DNA polymerase III holoenzyme  
 JOURNAL J. Bacteriol. 174, 7013-7025 (1992)  
 MEDLINE 93015766  
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